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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

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September 13, 2002

E. EDWARD KAVANAUGH
PRESIDENT

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20857

Re: Docket Number 02N-0209

Dear Sir/Madam:

The Cosmetic, Toiletry, and Fragrance Association (CTFA) is pleased to provide its comments in response to the Food and Drug Administration's (FDA's) "Request for Comment on First Amendment Issues." The ability to convey truthful and nonmisleading information about our products is of the highest importance to both consumers and CTFA members. There have been a number of judicial decisions in the recent past reminding FDA that it must apply First Amendment commercial speech principles to its decisions. This growing body of judicial opinions was recently reaffirmed by the Supreme Court in Thompson v. Western States Medical Center, 122 S. Ct. 1497 (2002). Thus, it is clearly time for FDA to evaluate its policies and specific decisions that restrict commercial speech and make the appropriate changes.

CTFA continues to have a strong interest in this subject and, therefore, as set forth in our comments, makes the following recommendations to FDA for prompt consideration and implementation in the context of a First Amendment analysis:

- FDA must re-evaluate and modify its OTC regulations with regard to the present lack of flexibility for labeling OTC drugs subject to a Final Monograph and FDA's recently enacted OTC drug labeling rule.

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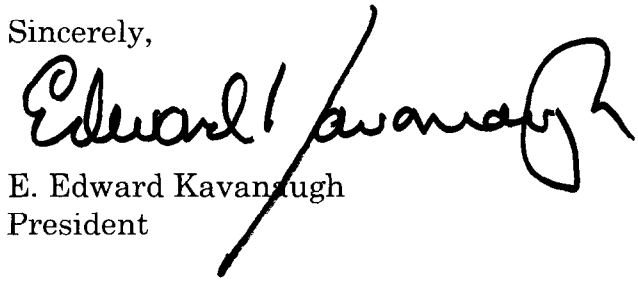
- FDA must re-evaluate and modify specific decisions in the Final Monograph for OTC sunscreen drug products related to limitations on Sun Protection Factor (SPF) claims and various labeling claims related to the positive impact of these products on the skin.

- FDA should articulate a new policy applicable to cosmetics and cosmetic-drugs to establish when commercial speech will be considered "inherently misleading."

CTFA appreciates FDA's requests for comment in this most critical area. The Supreme Court makes it crystal clear that FDA's traditional approach to decision making with regard to speech restrictions must change. CTFA looks forward to working with FDA on these matters.

Sincerely,



E. Edward Kavanaugh
President

HOGAN & HARTSON L.L.P.

September 13, 2002

THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

Response to the Food and Drug Administration's Request For Comment On First Amendment Issues

Public Docket No. 02N-0209

These comments are submitted on behalf of The Cosmetic, Toiletry, and Fragrance Association (hereafter "CTFA") 1/ in response to the United States Food and Drug Administration's ("FDA") request for comments on First Amendment issues and the way in which First Amendment protections for commercial free speech affect FDA regulatory activities.

For some time FDA has been active in regulating the speech manufacturers use to inform consumers about the uses and benefits of cosmetic and over-the-counter ("OTC") drug products. Most often this has taken the form of strictly limiting statements made on labels or requirements to use only agency-approved language in labeling for the products. In many circumstances, the First Amendment's protection of truthful, open communication between manufacturers and consumers has taken a back seat to the agency's paternalistic view that

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1/ CTFA is the national trade association representing the personal care product industry. With approximately 600 members, CTFA represents the interests of manufacturers and distributors of cosmetics and OTC drugs, as well as the companies supplying goods and services to those manufacturers and distributors. These companies participate in delivering products to market for use in promoting health, personal hygiene, and an attractive appearance. At least some of these products -- including cosmetic products like color cosmetics, skin lotions, and fragrances and OTC drug products such as sunscreens, antiperspirants, and antidandruff shampoos -- are used on a daily basis by virtually every consumer in the United States. FDA regulates some of these products as both cosmetics and drugs.

information about cosmetic and OTC products must be strictly limited to allow no room for potential consumer confusion or error.

As we will develop in this comment, in light of recent decisions, FDA should thoroughly review its approach and allow consumers more freedom to obtain truthful information relevant to their personal care and healthcare decisions. A more open approach is not only required by the Supreme Court's recent decision in Thompson v. Western States Medical Center, 122 S. Ct. 1497 (2002), but is also the fundamental premise for allowing certain drugs to be sold over-the-counter in the first place, so that consumers can make their own health and personal care decisions in appropriate circumstances.

CTFA has several specific concerns regarding FDA regulation of commercial speech in light of recent Supreme Court First Amendment decisions. The first relates to FDA's Over-the-Counter Drug Review and restrictions that the agency places on truthful and non-misleading claims for cosmetic-drug products. The second relates to FDA's re-evaluation of specific decisions related to sunscreens and OTC drug labeling format issues. And the third issue, which implicates both cosmetic and cosmetic-drug products, has to do with the standard FDA applies in analyzing whether the ordinary consumer is likely to be misled by the use of certain speech. We are particularly concerned that FDA's response to Western States may be to reflexively brand more speech as false or misleading, on the (untenable) assumption that consumers are not capable of evaluating labeling information when making their healthcare decisions. Such action would thwart the clear intent of the Supreme Court to increase, not restrict, the flow of information to consumers.

Each of the three areas CTFA has identified should be evaluated under the First Amendment framework set forth below.

I. THE SUPREME COURT'S COMMERCIAL SPEECH JURISPRUDENCE FULLY APPLIES TO FDA'S ACTIVITIES

A. Virginia Pharmacy Board and its Progeny

Information about a product offered for sale is "commercial speech" -- speech uttered to invite a commercial transaction. See Virginia Pharmacy Board v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 762 (1976). The Virginia Pharmacy Board decision, which struck down a state statute prohibiting the disclosure of pharmaceutical prices in advertisements, was the first to enunciate what would become a common refrain in the Court's First Amendment jurisprudence: "[P]eople will act in their own best interests if only they are well enough informed, and * * * the best means to that end is to open the channels of communication rather than to close them". Id. at 770.

In cases following Virginia Pharmacy Board, the Court elaborated on the standards pursuant to which restrictions on commercial speech would be reviewed. In Bates v. State Bar of Arizona, 433 U.S. 350 (1977), the Court struck down a state bar disciplinary rule prohibiting attorneys from advertising their services. The State of Arizona argued in Bates that attorney advertising was "inherently misleading," contending, among other things, that advertisements for legal services highlighted irrelevant information and failed to provide information about any individual attorney's level of skill. Id. at 372. The Court agreed with the State that advertisements did not provide a "complete foundation on which to select an attorney," id. at 374, but observed that the State bar was empowered to correct inaccurate information, and that in any event "the preferred remedy is more disclosure, rather than less". Id. at 375 (emphasis added).

The Supreme Court further refined its test for commercial speech in Central Hudson Gas & Electric Corp. v. Public Service Commission, 447 U.S. 557 (1980). There, the Court observed that the protection of a particular commercial expression under the First Amendment depends on "the nature both of the expression and of the governmental interests served by its regulation". Id. at 563. Misleading or false speech, or speech inviting an unlawful act, is not protected. But if the commercial speech at issue neither misleads nor relates to unlawful activity, the state's ability to regulate that speech is far more limited: it must demonstrate a "substantial interest" that is served by restricting the speech, and must also show that its regulation is proportional to its asserted interest. The regulation must directly advance the interest involved, and "excessive restrictions" on speech will not survive scrutiny. Id. at 564. In particular, a state may not "completely suppress information when narrower restrictions on expression would serve its interest as well". Id. at 565.

Central Hudson's holding can be summed up in a four-part test:

> For commercial speech to come within [the First Amendment], [1] it at least must concern lawful activity and not be misleading. Next, [2] we ask whether the asserted governmental interest is substantial. If both inquiries yield positive answers, we must determine whether [3] the regulation directly advances the governmental interest asserted, and [4] whether it is not more extensive than is necessary to serve that interest. [Id. at 566.]

The Court elaborated on the Central Hudson test's first element in In re R.M.J., 455 U.S. 191 (1982), reviewing a state Supreme Court rule prohibiting attorneys from advertising anything other than strictly defined categories of

information. The Court reiterated that regulation of commercial speech was permissible when the speech was "inherently likely to deceive or where the record indicates that a particular form or method of advertising has in fact been deceptive". Id. at 202. It cautioned, however, that while inherently misleading speech may be prohibited, the government "may not place an absolute prohibition on certain types of potentially misleading information * * * if the information also may be presented in a way that is not deceptive". Id. at 203. Reiterating the theme sounded in Bates, the Court explained that the preferred remedy for potentially misleading speech is "a requirement of disclaimers or explanation" -- not suppression. Id.; see also Peel v. Attorney Registration and Disciplinary Comm'n of Ill., 496 U.S. 91, 100-110 (1990) (state may ban advertisements which are "actually or inherently misleading", but the mere potential to mislead does not justify categorical prohibition on dissemination of accurate factual information to the public).

It is also clear that the burden rests with the government -- not the speaker -- to establish that the commercial speech at issue is false or inherently misleading. See Peel, 496 U.S. at 91. That bar is set very high. "For a particular mode of communication to be inherently misleading, it must be incapable of being presented in a way that is not deceptive." Revo v. Disciplinary Board of the Supreme Court for the State of New Mexico, 106 F.3d 929, 933 (10th Cir. 1997) (emphasis added). If commercial speech is only potentially misleading and may be presented in a manner that is not deceptive, First Amendment protections apply. See, e.g., Ibanez v. Florida Dep't of Business and Prof'l Reg., 512 U.S. 136, 146 (1994) ("If protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree"); In re R.M.J., 455 U.S. at 203.

The Court addressed step three of the Central Hudson test -- whether the regulation directly advances the government's stated interest -- in Edenfield v. Fane, 507 U.S. 761 (1993), a challenge to a state Board of Accountancy rule prohibiting certified public accountants from soliciting clients in person or over the telephone. The Court acknowledged the government's substantial interest in maintaining standards of ethical conduct in accountancy, but reiterated that under Central Hudson, the government "must demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree". Edenfield, 507 U.S. at 771 (emphases added). Because the government had not presented any evidence that its solicitation ban advanced its asserted interest "in any direct and material way" -- no studies or anecdotal evidence demonstrating fraud, overreaching, or compromised independence resulting from CPAs' solicitation of clients, for example -- the government's restriction could not stand. Id. See also Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995) (noting the "critical"

requirement that the government establish that challenged regulations advance its interest in a direct and material way); compare Florida Bar v. Went For It, Inc., 515 U.S. 618, 626-628 (1995) (noting "breadth and detail" of state bar's two-year study of lawyer advertising and direct-mail solicitation, and concluding that ban on mail solicitation in the immediate aftermath of accidents targeted a "concrete, nonspeculative harm").

Central Hudson's fourth prong -- whether the government's restriction on speech is no more expansive than necessary to advance its interests -- was clarified in Board of Trustees v. Fox, 492 U.S. 469 (1989), to be something short of the "least-restrictive-means" test employed in other First Amendment contexts. As the Fox Court put it, a restriction on commercial speech need not be "absolutely the least severe that will achieve the desired end," but still must reflect a reasonable "fit" between means and ends, a means "narrowly tailored to achieve the desired objective". Id. at 480. See also Anderson v. Treadwell, 294 F.3d 453 (2d Cir. 2002) (prohibition on "blockbusting" in specific residential areas -- soliciting home sales based on representations about the changing racial or ethnic character of a neighborhood -- satisfied Central Hudson's fourth prong because the law was "precisely coextensive" with the harm to residents' privacy interests that the government sought to alleviate).

Fox made clear that because the government bears the burden of justifying restrictions on commercial speech, it must likewise establish the "reasonable fit" required under Central Hudson's fourth prong. See 492 U.S. at 480. In cases following Fox, the Court stated that the government will have particular difficulty justifying its regulations if alternative, less intrusive forms of regulation could accomplish the same ends. In Rubin, for example, the Supreme Court rejected the government's argument that its prohibition on disclosures of alcohol content was sufficiently tailored to its goal of preventing alcohol "strength wars" among brewers. 514 U.S. at 490-491. The respondent brewer had advanced several alternatives to the prohibition on speech, "all of which could advance the Government's asserted interest in a manner less intrusive to the respondent's First Amendment rights". Id. at 491; see also City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 423 (1993) (whether "numerous and obvious less-burdensome alternatives to the restriction" existed was relevant consideration in determining reasonableness of regulations).

One year after Rubin, in 44 Liquormart v. Rhode Island, 517 U.S. 484, 507 (1996), the Court struck down a state statute banning advertisement of alcohol prices, finding it "perfectly obvious" that many less intrusive forms of regulation existed to accomplish the state's goal of "promoting temperance". And in 1999, the Court struck down a federal statute banning radio and television advertisements of private casino gambling in states where such gambling is legal, concluding that the statute "sacrifice[d] an intolerable amount of truthful speech about lawful conduct"

to advance governmental interests at best tenuously related to the restriction. Greater New Orleans Broadcasting Ass'n, Inc. v. United States, 527 U.S. 173, 175 (1999).

B. Western States

In Thompson v. Western States Medical Center, 122 S. Ct. 1497 (2002), the Court turned its attention to the regulation of commercial speech under the Food, Drug, and Cosmetic Act ("FDCA").

The case involved a challenge to Section 503A of the Food and Drug Administration Modernization Act ("FDAMA"), 21 U.S.C. § 353a. That provision exempted "compounded drugs" -- medications tailored to individual patient needs -- from the drug approval requirements, as long as the providers of compounded drugs refrained from advertising or promoting "any particular [compounded] drug, class of drug, or type of drug". Western States, 122 S. Ct. at 1500, 1502; 21 U.S.C. § 353a(c). A group of pharmacies specializing in drug compounding filed suit against FDA, arguing that the Act's prohibition on advertising specific compounding services violated the First Amendment.

The Supreme Court agreed. 122 S. Ct. at 1509. It began by retracing its steps in the commercial speech area back to Virginia Pharmacy Board and through Central Hudson, noting that the test articulated in the latter case still governed the inquiry when the government sought to regulate commercial speech. See Western States, 122 S. Ct. at 1504 (noting "no need to break new ground"). While the Court concluded that the government had articulated a substantial interest in ensuring that compounded drugs were not mass-produced in circumvention of new drug approval requirements, it found that the government had failed to carry its burden under Central Hudson's fourth prong: that is, the government had not "demonstrate[d] that the speech restrictions are 'not more extensive than those necessary to serve that interest.' " Western States, 122 S. Ct. at 1506. Reiterating its holdings in Rubin and 44 Liquormart, the Court stressed again that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so". Western States, 122 S. Ct. at 1506 (emphasis added). Pointing to several "non-speech-related" means of addressing the agency's articulated interest in ensuring that massive quantities of compounded drugs were not manufactured in avoidance of the new drug application requirements -- for example, banning the use of commercial-scale manufacturing equipment for compounding drug products -- the Court noted that the agency had not "offered any reason why these possibilities, alone or in combination, would be insufficient" to safeguard the government's interest. Id.

The Court closed by adding another strongly worded caution to its growing list of precedents: "If the First Amendment means anything, it means that

regulating speech must be a last -- not first -- resort. Yet here it seems to have been the first strategy that the Government thought to try." Id. at 1507.

The Supreme Court's decision in Western States confirms the Court's impatience with poorly thought-out governmental attempts to regulate commercial speech. The message from the Court could not have been clearer: the government bears the burden of justifying its regulation, and it must affirmatively prove that regulations limiting or banning speech are directed at concrete harms and are not imposed in disregard of other, less intrusive options.

The Supreme Court's mounting intolerance for reflexive regulation of commercial speech has been echoed in the D.C. Circuit and District Courts. In Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), the D.C. Circuit rejected FDA's attempt to prohibit health claims on dietary supplements unless the agency had concluded that such claims had "significant support" in medical literature. The court of appeals first dismissed the agency's argument that health claims with less than significant support were inherently misleading, concluding that the argument amounted to the near-"frivolous" assertion that health claims on dietary supplements so entranced the common consumer as to render him powerless to resist. See id. at 655. Acknowledging the FDA's interests in "ensuring the accuracy of commercial information in the marketplace" and in promoting public health, the court of appeals turned to Central Hudson's third and fourth prongs. Id. at 655. The court concluded that FDA's interest in public health was not at all advanced by the regulations when the agency had made no suggestion that the labeling claims at issue threatened public health, but that its alternative interest -- preventing consumer fraud -- was advanced by the agency's prohibition. Id. at 656. The agency's regulation, however, failed at the fourth Central Hudson step: in choosing to suppress speech rather than require more disclosure in the form of disclaimers, the court of appeals held, the agency had disregarded "'far less restrictive'" means of addressing its interest in preventing consumer fraud. Id. at 657 (quoting Fox, 492 U.S. at 479).

On remand, FDA declared in the face of the Court of Appeals' opinion that it nonetheless would not authorize the plaintiffs' dietary supplement claims relating to the benefits of folic acid, concluding that the claims were (in its view) "inherently misleading". Pearson v. Shalala, 130 F. Supp. 2d 105, 112 (D.D.C. 2001). On plaintiffs' motion, the District Court granted a preliminary injunction, concluding that FDA had "at best, misunderstood, and at worst, deliberately ignored, highly relevant portions of the Court of Appeals Opinion". Id. The District Court concluded that FDA's decision that the plaintiffs' health claims could not be cured by disclaimers was arbitrary and capricious, chiding the agency for completely "fail[ing] to consider clarifying disclaimers that could cure the alleged misleading nature of the Folic Acid Claim". Id. at 119. The trial court denied FDA's subsequent motion for reconsideration, again noting that the "arguments contained

in the motion for reconsideration further demonstrate [FDA's] reluctance to fully comply" with the D.C. Circuit's decision. Pearson v. Thompson, 141 F. Supp. 2d 105, 108 (D.D.C. 2001). As the District Court explained,

> the philosophy underlying [the D.C. Circuit's decision] is perfectly clear: that the First Amendment analysis in Central Hudson applies in this case, and that if a health claim is not inherently misleading, the balance tilts in favor of disclaimers rather than suppression. In its motion for reconsideration, the FDA has again refused to accept the reality and finality of that conclusion by the Court of Appeals. [Id. at 112.2/]

The Supreme Court's commercial speech cases from Virginia Pharmacy Board through Western States, as well as the recent D.C. Circuit and District Court decisions rejecting FDA's attempts to restrict commercial speech, contain familiar refrains: more information is heavily favored over less. When the government chooses to regulate truthful commercial speech, it bears the heavy burden of proving that its restriction is reasonably tailored and that it materially advances the interest the government claims. And paternalistic assumptions about the public's ability to process truthful information have no place in a decision to restrict commercial speech.

2/ Another attempt by FDA to regulate commercial speech was the subject of a challenge in district court. In Washington Legal Foundation v. Friedman, 13 F. Supp. 2d 51 (D.D.C. 1998), the district court held that the agency's policy statements restricting dissemination of information about "off-label" use of prescription drugs violated the First Amendment. The district court later reaffirmed that conclusion following enactment of the FDAMA, striking down the sections of that Act codifying with minimal changes the policy guidance the court earlier had found unconstitutional. See Washington Legal Foundation v. Henney, 1999 WL 557679 (D.D.C. July 28, 1999). On appeal, the D.C. Circuit vacated the district court's decisions after FDA conceded at oral argument that the FDAMA did not confer independent authority on the agency to proscribe speech; the court nonetheless took pains to note that it "certainly d[id] not criticize the reasoning or conclusions of the district court." Washington Legal Foundation v. Henney, 202 F.3d 331, 336-337 & n.7 (D.C. Cir. 2000).

II. THE GOVERNMENT'S INTEREST IN REGULATING COMMERCIAL SPEECH RELATING TO COSMETICS AND COSMETIC-DRUGS MUST BE WEIGHED AGAINST THE PROTECTIONS OF THE FIRST AMENDMENT

A. The Regulation of Cosmetics and Cosmetic-Drugs

With respect to cosmetic products marketed in interstate commerce, the FDCA prohibits them from being adulterated or misbranded. 21 U.S.C. §§ 361, 362. The adulteration standards, among other things, prohibit a cosmetic from bearing or containing a poisonous or deleterious substance which may render the product injurious to users under the conditions of use prescribed or from being prepared, packed or held under unsanitary conditions whereby it may have become contaminated with filth. A cosmetic is misbranded if, among other things, its labeling is false or misleading in any particular; or the labeling does not contain certain information including the name and address of the manufacturer; or any word, statement or other required information on the label or labeling is not prominently placed so as to be read and understood by the consumer. 21 U.S.C. § 362 (a)-(c). Cosmetic products, unlike new drugs, are not subject to any pre-approval requirements prior to marketing. Color additives used in cosmetic products, on the other hand, must be pre-approved by FDA. It is accordingly through the FDCA's misbranding provisions that FDA regulates speech for all marketed cosmetics.

All drug products marketed in interstate commerce are subject to three core requirements under the FDCA. First, a drug cannot be "adulterated" within the meaning of section 501 of the FDCA. It must, among other things, be free of filth or deleterious matter, and it must be manufactured in accordance with "good manufacturing practice" standards. See 21 U.S.C. § 351(a)-(d).

Second, a drug marketed in interstate commerce must not be "misbranded" within the meaning of section 502 of the FDCA. Among other things, the labeling of the drug must contain certain minimal information, including the manufacturer's name and place of business, the established name of the drug, quantity and content information, and adequate directions or information on the proper use of the drug. See 21 U.S.C. § 352(b), (e), (f). In addition, the labeling of the product cannot be "false or misleading in any particular," and cannot omit information that may be material to the consumer under "customary or usual" conditions of use. See 21 U.S.C. §§ 352(a), 321(n).

Third, if a drug is a "new drug" within the meaning of section 201(p) of the FDCA, it must be the subject of an approved new drug application submitted under section 505 of the FDCA. See 21 U.S.C. §§ 321(p), 355(a). A drug is a "new drug" if experts have not "generally recognized" the drug to be safe and effective for

its labeled uses, or if the drug has not been marketed "to a material extent" or "for a material time" for such uses. See 21 U.S.C. § 321(p). As a general matter, FDA considers all prescription drug products to be new drugs. Only products marketed directly to consumers as "over-the-counter" or "OTC" drugs are eligible for "not new drug" status. See 67 Fed. Reg. 3060 (Jan. 23, 2002) and related notices (discussing eligibility criteria for classifying drugs as "new" or "not new" under section 201(p)); see also 21 U.S.C. § 353(b) (setting standard for determining whether a drug may be marketed OTC or by prescription only). And as discussed further below, there are a number of product categories which, based upon claims made, are regulated as both cosmetics and OTC drugs (hereafter referred to as "cosmetic-drugs").

It is through the second and third requirements -- the misbranding requirement and the new drug requirement -- that FDA regulates the speech of all marketed drugs, including cosmetic-drugs. For example, FDA prescribes the conditions of use for which drug products may be labeled in order to avoid being deemed misbranded or regarded as new drugs. FDA has defined a condition as "any active ingredient, indication, dosage form, dosage strength, route of administration, active ingredient combination, or any combination of these conditions". See 61 Fed. Reg. 51625, 51627 (October 3, 1996). FDA's control over the expression of the conditions of use that may be attributed to a particular drug product is even more pronounced than that definition suggests. Indeed, in establishing the parameters under which an OTC drug may be generally recognized as safe and effective and not misbranded, FDA dictates virtually every condition of use related to the labeling and marketing of such a product, including the statement of identity, indications, warnings and directions that must appear on the product's labeling. 21 C.F.R. § 330.1. And the agency goes still further: not only must the meaning of the language that appears on labeling fall within the scope of what the agency has deemed acceptable, but the precise language specified by FDA must be used in all circumstances "where exact language has been established and identified by quotation marks in an applicable OTC monograph or by regulation". 21 C.F.R. § 330.1(2).

B. The OTC Drug Review Labeling Requirements

CTFA has two concerns about FDA's limited flexibility in the language a manufacturer may use. First, the flexibility in the choice of truthful, nonmisleading language is not uniform. The statement of identity and warnings language must be identical to that contained in FDA's Final Monograph. Only limited flexibility exists for directions for use and indications. Second, this limited flexibility comes at the end of the OTC Review Process, when FDA publishes a Final Monograph. In many cases, that process has resulted in a significant narrowing by FDA of acceptable language, which, as discussed above, was not rigidly enforced under FDA's Compliance Policy Guide for the often-lengthy time period before issuance of a particular Final Monograph.

As outlined above, the FDCA draws a distinction between "new drugs" and all other drugs. Only "new drugs" require premarket approval by FDA. All other drugs, including most OTC cosmetic-drugs, may be introduced into interstate commerce without premarket approval.

In 1972, FDA created the OTC Drug Review as a process for establishing the "conditions" under which OTC drugs within various classes would be considered "generally recognized" for purposes of section 201(p) and not misbranded for purposes of section 502. A drug deemed generally recognized as safe and effective or "GRAS/E" does not require premarket approval. Among the classes of drugs included in the review were cosmetic-drug categories such as sunscreen products, antidandruff products, antiperspirants, and oral care products.

The "conditions" that FDA established under the OTC Drug Review are memorialized in "monographs," published beginning at 21 C.F.R. Part 330, and extend to every facet of the required labeling for a given product. The names of active ingredients, the identity of the product, the allowable uses, the necessary warnings, and the prescribed directions are all established by regulation. OTC drugs that comply with the specifications of a final monograph and other general labeling requirements are considered GRAS/E and not misbranded. See 21 C.F.R. §§ 330.1, 201.66. However, when a product is determined to have strayed from a particular monograph, FDA then regards the product as an "unapproved new drug" and a misbranded drug, the distribution of which is strictly prohibited. See 21 U.S.C. § 321(a), (d), (k). The distribution of an unapproved or misbranded drug in interstate commerce is subject to civil and criminal liability under the FDCA. See 21 U.S.C. §§ 332, 333, 334. 3/

When the agency initiated the OTC Drug Review in 1972, FDA predicted that within three to five years it would have completed the evaluation of all marketed OTC drugs and published standards for each major class of products. In fact, 30 years later, more than half of the categories lack finished monographs, including major cosmetic-drug categories such as sunscreens, and skin protectants.

FDA has maintained a Compliance Policy Guide ("CPG") which accepts significant flexibility in labeling for OTC drug products subject to a monograph before completion of the OTC Review for a particular product category. See CPG 7132b.15, "General Provisions and Administrative Procedures for Recognition as Safe and Effective". For these specific products still awaiting a final monograph, FDA allows them to continue to be marketed if they either (1) conform to the conditions that FDA has proposed (but not finalized), or (2) were marketed as an

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3/ These comments address only cosmetic-drugs subject to one or more monographs. They are not intended to address OTC drug products properly considered to be "new drugs" requiring specific approval.

OTC drug for the conditions expressed in the labeling on or before December 4, 1975 (May 11, 1972 for products with multiple active ingredients) and do not present a danger to the health of the user. With respect to the labeling of such products, FDA itself has stated that it is not in the agency's interest to pursue regulatory action based on a labeling deficiency unless the failure to do so poses a potential health hazard to the consumer. FDA cites "drugs requiring the prescription legend marketed as OTC, and unwarranted claims for the treatment of serious disease conditions which could preclude obtaining proper medical attention" as labeling deficiencies that could pose a health hazard Id.

FDA's policy allowing flexibility in OTC drug labeling for products subject to a monograph during the pendency of the OTC Review process for a particular product category suggests that such flexibility in labeling satisfies the government's interest, as long as labeling does not pose a health hazard. The question FDA should address, in the context of a First Amendment analysis, is why flexibility afforded to OTC drugs prior to a Final Monograph must suddenly give way to rigid language requirements at the completion of the rulemaking process.

C. The Limited Labeling Flexibility Under The OTC Monographs At Present Is Not Useful

The OTC Monographs set forth labeling requirements for the statement of identity, uses, warnings, and directions for use for OTC drugs subject to the monographs. The OTC regulations, however, impose different requirements on these sections with respect to the degree with which product labels must use the precise language in a monograph. While FDA permits manufacturers some flexibility in selecting precise labeling language for uses included within a final monograph, the uncertainty associated with exercising that flexibility makes it largely unusable.

Until 1999, FDA followed an "exclusivity policy" in which manufacturers of OTC drugs generally were required to follow the precise language of the final monograph prescribed by the agency. The 1973 final monograph for antacids, for example, prohibited using indications other than the ones in the monograph because "the terms recommended by the Panel fully meet the intent of the regulation. Allowing each manufacturer to select the words to be used would result in continued consumer confusion and deception". 38 Fed. Reg. 31260, 31264 (1973). FDA further clarified that the indications section of an OTC antacid label must use "the specified terms permitted by the regulation." 40 Fed. Reg. 11718 (1975). Over time, comments objecting to the exclusivity policy were submitted to various OTC rulemaking proceedings. Those objecting asserted that the exclusivity policy was "unduly restrictive, unconstitutional, and contrary to the purpose of the Federal Food, Drug, and Cosmetic Act in that it prevents manufacturers from using truthful alternative wording". 47 Fed. Reg. 29002 (1982).

Eventually a hearing was granted in response to petitions filed as part of the nighttime sleep-aid and stimulant drug products monograph proceedings. Id. at 29003. As a result of the hearing, and in conjunction with the agency's completion in March 1999 of a standardized format for all OTC drug products, the agency has allowed some labeling flexibility. For information such as the statement of identity and warnings, FDA still requires manufacturers to use the precise language prescribed by the agency. For directions, the manufacturer is given some flexibility to use alternative words to express the same dosing regimen (e.g., "Take 1 tablet every 8 hours" and "Take no more than three tablets in a 24 hour period").

With respect to describing the uses of a product, the agency offered, in March 1999, what appeared to be a much greater degree of flexibility. According to the agency,

> [t]he "Uses" section of the label and labeling of the product shall contain the labeling describing the "Indications" that have been established in an applicable OTC drug monograph or alternative truthful and nonmisleading statements describing only those indications for use that have been established in an applicable monograph. * * * Any other labeling under this subchapter and subchapter C et seq. of this chapter shall be stated in the exact language where exact language has been established and identified by quotation marks in an applicable OTC drug monograph or by regulation (e.g., Sec. 201.63 of this chapter), except as provided in paragraphs (i) and (j) of this section.

21 C.F.R. § 330.1(c).

III. FDA DECISIONS MUST BE RE-EVALUATED IN LIGHT OF FIRST AMENDMENT PRINCIPLES

Before CTFA makes specific recommendations as to what steps FDA should take to consider First Amendment principles in its future decision-making, it may be useful to illustrate certain FDA decisions already made that require re-evaluation. In addition, we will discuss our serious concern that FDA may approach all future labeling decisions in a way that could improperly evade the application of the First Amendment to such decisions.

A. Sunscreens

In 1978, FDA published its initial Panel Report on OTC sunscreens. In 1993, FDA published a Tentative Final Monograph ("TFM") proposing conditions under which OTC sunscreens would be generally recognized as safe and effective.

58 Fed. Reg. 28194 (May 12, 1993). Among other things, the TFM announced the agency's intent to limit the Sun Protection Factor ("SPF") value of sunscreen products to 30. Id. at 28223-25. Although FDA acknowledged that sunscreens with SPF values over 30 blocked a higher percentage of Ultra Violet B ("UVB") rays than SPF 30 sunscreens, the agency nonetheless concluded that SPF values were "not necessary," because "a sunscreen drug product with an SPF of 30 assures adequate protection for the majority of consumers even under extreme conditions". Id. at 28225.

In the 1993 TFM, FDA also endorsed the position of the advisory panel that exposure to Ultra-Violet ("UV") radiation contributed to premature aging of the skin. Id. at 28226-27. Agreeing with the advisory panel that "consumers should be alerted to the risks of premature skin aging * * * due to exposure to the sun," the agency proposed to allow manufacturers to make certain claims regarding the ability of sunscreen products to mitigate the effects of sun exposure on the skin. Id. at 28287. While certain claims were considered unacceptable by FDA because they were too broad or ambiguous, FDA proposed several claims it stated would be acceptable for use on sunscreen labels (e.g., "sunscreen may reduce the chance of skin aging caused by exposure to the sun," or "sunscreen may help protect skin from aging caused by exposure to ultraviolet radiation from the sun"). Id. In addition to suggesting non-mandatory language regarding the benefits of sunscreens to protect against skin aging caused by UV exposure, FDA's proposed regulations allowed manufacturers to select from one of several mandatory "indications for use" of sunscreen-containing products, ranging from indications particularly appropriate for sunscreens (e.g., that a product "prevents sunburn") to those more appropriate for cosmetics containing sunscreens as an additional element of skin protection (e.g., stating that a product "screens out the sun's harmful rays to help prevent skin damage, freckling, or uneven coloration").

Importantly, the TFM also proposed requiring manufacturers to include language that the FDA thought combined "the attributes of an indication and a warning". The proposed mandatory Sun Alert stated: "SUN ALERT: the sun causes skin damage. Regular use of sunscreens over the years may reduce the chance of skin damage, some types of skin cancer, and other harmful effects due to the sun". The agency also proposed an additional regulation stating that any language in sunscreen products' labeling that did not equate skin aging as being "due to the sun" would cause the products to be misbranded.

On May 21, 1999, FDA published a Final Monograph establishing conditions under which certain OTC sunscreen products would be generally recognized as safe and effective and not misbranded. 64 Fed. Reg. 27666. FDA concluded in its final rule that sunscreen products with SPF values above 30 provided additional protection from the sun, did not present safety problems due to their chemical concentrations, and should be made available to consumers. But

while FDA agreed that manufacturers could market sunscreens with SPF values over 30, the final rule prohibited manufacturers from disclosing what those actual values were. Rather, for sunscreen products with SPFs over 30, FDA would require manufacturers to use a collective term, either "SPF 30 plus" or "SPF 30+," when describing such a product. The final rule stated that if manufacturers disclosed actual SPF values over 30 on their sunscreen products, the agency would consider the products to be misbranded under the FDCA. FDA's prohibition against disclosure of SPF values over 30 on sunscreens suppresses truthful speech about such products by their manufacturers.

FDA also announced in its final rule that manufacturers of sunscreen products were prohibited from making any claims about their products' use in retarding photoaging of the skin, concluding that indications for use beyond "preventing sunburn" were "unsupported". Id. at 27677. FDA's new and far more restrictive indications for use -- which eliminated the proposed rule's allowances for claims regarding the prevention of skin damage -- prohibits manufacturers of cosmetic-drug products from making truthful claims about their products.

In a very troubling additional about-face from the TFM, FDA revised the language of the Sun Alert, concluding that a manufacturer could provide the consumer with information about the role of sunscreens in reducing skin aging only through specific words that the FDA concluded would ensure that such information would not be misleading. The final version of the "Sun Alert" -- which manufacturers must reprint verbatim, if they wish to make such a claim, to avoid a charge of misbranding -- reads: "Limiting sun exposure, wearing protective clothing, and using sunscreens may reduce the risks of skin aging, skin cancer, and other harmful effects of the sun". Manufacturers are forbidden from making any reference to skin aging aside from the "Sun Alert".

In December 2001, FDA published a partial stay of the final rule to consider a number of technical issues related to sunscreens. 66 Fed. Reg. 67485 (Dec. 31, 2001). FDA should reevaluate the stayed Sunscreen Final Rule against the Western States principles set forth above, as we explain in more detail in section V.A. below.

B. OTC Drug Labeling Format for Cosmetic-Drugs

In February 1997, FDA issued a sweeping proposal to change the labeling of OTC drug products. See 62 Fed. Reg. 9024 (Feb. 27, 1997). In the Proposed Rule, FDA sought to establish a standardized format for presenting FDA-required information on the label or labeling of OTC drug products, including cosmetic-drugs. FDA purported to act under Section 502 of the Act, the provision concerning "misbranding" of OTC drugs. 21 U.S.C. § 352(c). The principal basis cited by the agency in issuing the Proposed Rule was the need "to enable consumers to better read and understand OTC drug product labeling and to apply [the]

information [on such labeling] to the safe and effective use of OTC drug products". 62 Fed. Reg. at 9024.

In determining that new OTC drug labeling requirements were necessary, FDA cited concerns that OTC drugs have become increasingly available in more potent forms, as drugs have been and are expected to continue to be switched from prescription to OTC status; that more consumers are practicing self-diagnosis and self-medication as a result; and that the potential for misuse and adverse drug reactions -- particularly among the elderly -- has increased. Id. at 9027-28.

Numerous comments in response to the Proposed Rule from industry, consumer, and health professional organizations urged the agency to remain flexible in imposing format requirements. In extensive comments submitted to the agency, CTFA demonstrated that the data cited by FDA in support of the OTC labeling requirements did not support application of the requirements to cosmetic-drug products without dosage limitations -- such as antiperspirant/deodorants and sunscreens -- because those products plainly do not raise the health and safety concerns that prompted FDA to issue the Proposed OTC Drug Labeling Format Rule. As CTFA explained, such products are used by consumers on a daily or even more frequent basis, and have an exceptionally long history of widespread safe and effective use. Unlike many of the OTC drug products that the agency examined in issuing the Proposed Rule, see id. at 9027, cosmetic-drug products without dosage limitations have not been switched from prescription to OTC drug status.

CTFA also urged FDA to exempt small packages from the final OTC labeling requirements. As CTFA explained, the proposed requirements would make it difficult for cosmetic-drug products to include information required for both drugs and cosmetics, and leave little room for the cosmetic information that is of great interest to consumers of such products.

FDA published its Final Rule in March 1999. 64 Fed. Reg. 13254 (Mar. 17, 1999). The rule establishes standardized format and content requirements for the labeling of OTC drug products -- including cosmetic-drugs without dosage limitations -- and imposes detailed, inflexible format requirements for presenting FDA-required information on the label or labeling of OTC drug products. Among the requirements specified are the placement of information and the usage of type style, leading, kerning, bullets, barlines, and hairlines. 64 Fed. Reg. at 13288; see 21 C.F.R. § 201.66.

In the preamble to the Final Rule, FDA summarily rejected all of CTFA's comments without articulating a rationale for imposing the Final Rule on cosmetic-drug products without dosage limitations. FDA did not cite any additional data supporting the application of the Final Rule to such products. FDA also failed

to provide the exemption from the OTC drug labeling requirements for small packages of cosmetic-drugs, as CTFA had requested. The agency concluded that the modified labeling format will allow most packages to comply with the OTC labeling requirements, and the packages that cannot otherwise comply can use design techniques to increase labeling space. See 64 Fed. Reg. at 13268. FDA again failed to provide a substantive response to CTFA's comments about the need for a small package exemption. The agency provided no substantive explanation for its refusal to adopt a more objective standard for determining that a package is "small," as CTFA had also proposed, nor did it consider alternatives to its decision.

IV. FDA'S APPROACH TO EVALUATING "FALSE AND MISLEADING" SPEECH FOR COSMETICS AND COSMETIC-DRUGS SHOULD BE CHANGED

The government's defense in Western States was based on prongs two, three, and four of the Central Hudson four-prong test: it defended the pharmacy compounding provision at issue there by attempting to show a "substantial government interest" and a regulatory solution that "directly advances" that interest and that was no more restrictive than necessary. As the Court in Western States noted at the outset, the government did not "attempt to defend the FDAMA's speech-related provisions under the first prong of the Central Hudson test, i.e., it does not argue that the prohibited advertisements would be about unlawful activity or would be misleading". Western States, 122 S. Ct. at 1504.

Having lost Western States, and having had no luck with a similar approach in the Pearson cases in the D.C. Circuit and District Courts, in the future FDA may shift its focus to the first prong of Central Hudson: that is, it may attempt to categorize the speech at issue as being about an unlawful activity -- such as putting an unapproved or misbranded drug into commerce -- or it may attempt to argue that certain labeling claims are inherently misleading, either of which would end the Central Hudson inquiry. FDA should evaluate such an approach carefully. In certain narrow circumstances, such judgments may well be appropriate. But in many if not most situations, FDA will instead be confronted with decisions that are, at best, related to commercial speech that is only potentially misleading. In those circumstances, FDA is obligated to conduct a full Central Hudson analysis.

V. RECOMMENDATIONS

A. FDA Should Re-Evaluate Its OTC Drug Labeling Rules

While the FDA has adopted a policy of limited flexibility over the years with respect to certain aspects of the required labeling for OTC drugs subject to a Final Monograph -- including cosmetic-drugs -- it remains rigid with regard to

labeling requirements. The net effect of such limited flexibility in OTC drug labeling is to make it impracticable in actual use. FDA should re-evaluate these policies, particularly in light of the Supreme Court's recent admonition in Western States. CTFA is not advocating that companies be allowed to make new claims that turn these products into "new drugs" requiring pre-approval. Rather, CTFA believes that once FDA sets all the conditions of use in a Final Monograph, a manufacturer should be allowed to convey that information in any truthful, nonmisleading manner that the manufacturer deems appropriate.

This is what FDA has allowed by application of its Compliance Policy Guide to product categories where no Final Monograph presently exists. FDA must bear the burden of explaining why this long-held flexibility policy is no longer applicable, and why rigid labeling requirements for a new Final Monograph product category are suddenly necessary to achieve its governmental interests. As the Supreme Court has made clear time and again, the burden on government is a heavy one. Unless the speech at issue is "actually or inherently misleading," Peel, 496 U.S. at 110, the presumption embedded in the Court's First Amendment commercial-speech jurisprudence is that methods short of a total ban on speech will suffice to protect the government's interest. The preferred remedy for speech that is even potentially misleading is "a requirement of disclaimers or explanation" -- not suppression. R.M.J., 455 U.S. at 203.

FDA should revisit its refusal to allow flexibility in the labeling format and to allow for a reasonable small package exemption for cosmetic-drugs. The agency reached those final decisions with little or no factual analysis of the basis for these restrictions as they relate to cosmetic-drugs. Nor did the agency conduct any analysis of whether alternative, less restrictive approaches could meet its interests.

B. FDA Should Through Specific Decisions And With Specific Supporting Data Bear The Burden Of Proof In Restricting Commercial Speech

In the specific decisions FDA has made restricting commercial speech -- for example, its decisions regarding sunscreen products with an SPF over 30, its severe limitations on acceptable premature aging claims, its overly restrictive Sun Alert statement and rigid cosmetic-drug labeling and package formats -- the FDA's speech restrictions have been conclusory and unsupported, with little or no data bolstering the agency's conclusion that it must restrict speech rather than allow a suitable disclaimer or other flexibility in format that does not result in misleading consumers. Nor are there any indications that the agency considered lesser restrictions -- or in the case of labeling formats, different formats -- as a means of achieving its interests. FDA has simply asserted that its restrictions result from its general judgment that such commercial speech is misleading.

The Supreme Court made clear in Western States that the agency may not employ such conclusory judgments when it bans or restricts commercial speech, chiding the agency for failing to "offer[ ] any reason" why less restrictive, non-speech-related possibilities, "alone or in combination, would be insufficient" to safeguard the government's interest. 122 S. Ct. at 149. Rather than contenting itself with regulating speech as the "first strategy that the Government thought to try," the agency should fully embrace the Court's holding in Western States that a restriction on speech is to be used only as a "last resort," after less restrictive means -- such as disclaimers or explanatory statements -- have been fully considered and reasonably rejected. Id. at 1507. The agency should revisit its conclusory and unsupported decisions restricting commercial speech, and it should conduct a full Central Hudson analysis.

C. FDA Should Articulate A New Policy Applicable To Cosmetics And Cosmetic-Drugs To Establish When Commercial Speech Will Appropriately Be Deemed "Inherently Misleading"

Many remain concerned that future FDA decisions banning or restricting labeling claims on cosmetics or cosmetic-drugs will be based on conclusory judgments that such speech is "inherently misleading". As discussed above, by taking this route, the agency might intend to avoid the remainder of the Central Hudson balancing test and not adequately consider constitutional protection for commercial speech. FDA should develop some general principles that it will apply to such decisions in the future. Those principles should in no way limit FDA's ability to ban inherently misleading commercial speech; rather, they would guide FDA employees and industry in day-to-day determinations as to whether labeling information is potentially useful to consumers, or so inherently misleading as to conflict with the government's consumer protection mission.

Any new FDA policy statement outlining what is "inherently misleading" should contain three basic elements. First, FDA should acknowledge that it bears the burden of proving -- not just conclusorily asserting -- that the commercial speech at issue is inherently misleading. See Ibanez, 512 U.S. at 146. Second, if commercial speech is only potentially misleading, FDA must fully consider the use of disclaimers or other less restrictive means to address the issue. Third, as part of its assessment as to whether particular commercial speech is misleading, the FDA should adopt the Federal Trade Commission's deception policy, as detailed below, where appropriate.

The FTC is tasked with protecting consumers from deceptive claims in advertising. This statutory charge reflects a Congressional judgment that advertising, like labeling, should not deceive consumers with false or misleading claims. The FTC, like FDA, must pursue its mission in a manner consistent with the First Amendment. An advertisement is deceptive if the FTC establishes that

there is a representation, omission or practice that is likely to mislead consumers acting reasonably under the circumstances and is material to the consumer's purchasing decision. This so-called "reasonable person" standard, adopted by the Commission in 1983, replaced the FTC's more restrictive standard whereby deceptive claims were those that had the "tendency or capacity" to mislead. The "reasonable person" standard has been widely upheld by reviewing courts. See, e.g., Figgie International, Inc., 107 F.T.C. 313 (1986), aff'd, 817 F.2d 102 (4th Cir. 1987); Thompson Medical Co., 104 F.T.C. 648 (1984), aff'd, 791 F.2d 189 (D.C. Cir. 1986), cert. denied, 479 U.S. 1086 (1987). The Commission's adoption of this guidance has proven valuable to the FTC staff and industry alike in ensuring appropriate protection of commercial speech that is truthful and not misleading.

The FTC's Policy Statement on Deception advises that the test is "whether the consumer's interpretation or reaction is reasonable," and it makes clear that "a company is not liable for every interpretation or action by a consumer". See Policy Statement on Deception, appended to Cliffdale Associates, Inc., 103 F.T.C. 110, 174-184 (1984). The Policy Statement references a prior Commission decision to reinforce the pertinent standard: "An advertiser cannot be charged with liability with respect to every conceivable misconception, however outlandish, to which his representations might be subject among the foolish or feeble-minded. Some people, because of ignorance or incomprehension, may be misled by even a scrupulously honest claim." Id. at 178 (quoting Heinz W. Kirchner, 63 F.T.C. 1282, 1290 (1963), aff'd, 337 F.2d 751 (9th Cir. 1964)). Moreover, FTC has long recognized that the sophistication of the audience is relevant in evaluating whether a claim is deceptive. Id. at 178-179.

The limits on FTC's discretion in interpreting claims reasonably conveyed by an advertisement are well-established. The Commission "may not inject novel meanings into ads and then condemn them as unsupported". Of course, the courts have deferred to FTC's judgment when it properly finds that a claim is in fact deceptive. 4/

Courts have not hesitated, however, to reject the FTC's attempts to ban speech in circumstances where the claim at issue was only potentially misleading, even when the Commission has argued that the statement was inherently misleading. Indeed, in the 1970s, a series of court rulings overruled several attempts by the FTC to ban commercial speech outright. For example, the Third Circuit overruled the FTC when the Commission banned the use of "Instant Tax Refund" by a firm that offered loans to individuals based on anticipated tax refunds. The court held that it was an abuse of discretion for the FTC to bar future use of "Instant Tax Refund," without fully considering whether modification of the

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4/ The FTC, for example, has held that a claim which deceives a large minority of consumers is unlawful. Id. at 177 n.20.

message could eliminate the deception. Rejecting the FTC's position that the statement was inherently misleading, the court noted that modification of the statement is to be preferred over excision. Beneficial Corporation v. FTC, 542 F.2d 611, 619 (3d Cir. 1976) (citing Jacob Siegel Co. v. FTC, 327 U.S. 608 (1946) (holding that the FTC abused its discretion in ordering excision from advertising of a trade name without considering whether modification of the message would eliminate the objectionable portion) and FTC v. Royal Milling Co., 288 U.S. 212 (1933) (same)).

These FTC decisions that apply a reasonable consumer standard square exactly with the Supreme Court's repeated teachings in the commercial speech arena from Virginia Pharmacy through Western States. As we explained above, the preferred remedy for potentially misleading speech is not to ban it altogether, but to permit it to be uttered with -- if necessary -- a disclaimer, explanatory statement, or other contextual information helpful in mitigating the potential confusion. See Western States, 122 S. Ct. at 1507; Peel, 496 U.S. at 110; R.M.J., 455 U.S. at 203. Only where the commercial speech is actually or inherently misleading -- meaning that it is "incapable of being presented in a way that is not deceptive," Revo, 106 F.3d at 933 -- may the government employ the "last resort" measure of restricting or banning the speech. Western States, 122 S. Ct. at 1507.

VI. CONCLUSION

The Western States decision reaffirms and strengthens the First Amendment principles that FDA must apply when making any decision to restrict what companies may say about their lawful products. The Supreme Court has made it quite clear that FDA's traditional ways of considering these matters must change. FDA must consider alternatives to any such restrictions and it bears a heavy burden to establish that its decisions are appropriate under the First Amendment.

CTFA has identified three areas of FDA activity where the Supreme Court's principles must be applied:

- The flexibility in language and labeling formats available to OTC drugs;
- The flexibility in language available to OTC sunscreen drug products;
- The policies that FDA must apply before reaching a decision that product labeling is inherently misleading.

A meaningful evaluation of these issues applying the First Amendment principles set forth in these comments will result in modifications to FDA decisions and policies.

John G. Roberts, Jr.

Robert P. Brady